5.5 Medically Ineffective Interventions

At times patients (or their surrogates) request interventions that the physician judges not to be medically appropriate. Such requests are particularly challenging when the patient is terminally ill or suffers from an acute condition with an uncertain prognosis and therapeutic options range from aggressive, potentially burdensome life-extending intervention to comfort measures only. Requests for interventions that are not medically appropriate challenge the physician to balance obligations to respect patient autonomy and not to abandon the patient with obligations to be compassionate, yet candid, and to preserve the integrity of medical judgment.

Physicians should only recommend and provide interventions that are medically appropriate—*i.e.,* scientifically grounded—and that reflect the physician's considered medical judgment about the risks and likely benefits of available options in light of the patient's goals for care. Physicians are not required to offer or to provide interventions that, in their best medical judgment, cannot reasonably be expected to yield the intended clinical benefit or achieve agreed-on goals for care. Respecting patient autonomy does not mean that patients should receive specific interventions simply because they (or their surrogates) request them.

Many health care institutions have promoted policies regarding so-called "futile" care. However, physicians must remember that it is not possible to offer a single, universal definition of futility." The meaning of the term "futile" depends on the values and goals of a particular patient in specific clinical circumstances.

As clinicians, when a patient (or surrogate on behalf of a patient who lacks decision-making capacity) request care that the physician or other members of the health care team judge not to be medically appropriate, physicians should:

(a) Discuss with the patient the individual's goals for care, including desired quality of life, and seek to clarify misunderstandings. Include the patient's surrogate in the conversation if possible, even when the patient retains decision-making capacity.

(b) Reassure the patient (and/or surrogate) that medically appropriate interventions, including appropriate symptom management, will be provided unless the patient declines particular interventions (or the surrogate does so on behalf of a patient who lacks capacity).

(c) Negotiate a mutually agreed-on plan of care consistent with the patient's goals and with sound clinical judgment.

(d) Seek assistance from an ethics committee or other appropriate institutional resource if the patient (or surrogate) continues to request care that the physician judges not to be medically appropriate, respecting the patient's right to appeal when review does not support the request.

(e) Seek to transfer care to another physician or another institution willing to provide the desired care in the rare event that disagreement cannot be resolved through available mechanisms, in keeping with ethics guidance. If transfer is not possible, the physician is under no ethical obligation to offer the intervention.

As leaders within their institutions, physicians should encourage the development of institutional policy that:

(f) Acknowledges the need to make context sensitive judgments about care for individual patients.

(g) Supports physicians in exercising their best professional judgment.

(h) Takes into account community and institutional standards for care.

(i) Uses scientifically sound measures of function or outcome.

(j) Ensures consistency and due process in the event of disagreement over whether an intervention should be provided.

AMA Principles of Medical Ethics: I,IV,V

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report 2-I-6 Medical futility in end of life care

CEJA Report 2-A-94 Futile care [opinion]

5.5 Medically Ineffective Interventions

At times patients (or their surrogates) request interventions that the physician judges not to be medically appropriate. Such requests are particularly challenging when the patient is terminally ill or suffers from an acute condition with an uncertain prognosis and therapeutic options range from aggressive, potentially burdensome life-extending intervention to comfort measures only. Requests for interventions that are not medically appropriate challenge the physician to balance obligations to respect patient autonomy and not to abandon the patient with obligations to be compassionate, yet candid, and to preserve the integrity of medical judgment. [New content sets out key ethical values and concerns explicitly.]

Physicians should only recommend and provide interventions that are medically appropriate—*i.e., scientifically grounded*—and that reflect the physician's considered medical judgment about the risks and likely benefits of available options in light of the patient's goals for care. Physicians are not required to offer or to provide interventions that, in their best medical judgment, cannot reasonably be expected to yield the intended clinical benefit or achieve agreed-on goals for care. Respecting patient autonomy does not mean that patients should receive specific interventions simply because they (or their surrogates) request them.

Many health care institutions have promoted policies regarding so-called "futile" care. However, physicians must remember that it is not possible to offer a single, universal definition of futility." The meaning of the term "futile" depends on the values and goals of a particular patient in specific clinical circumstances.

As clinicians, when a patient (or surrogate on behalf of a patient who lacks decision-making capacity) request care that the physician or other members of the health care team judge not to be medically appropriate, physicians should: *[New content clarifies context of guidance.]*

(a) Discuss with the patient the individual's goals for care, including desired quality of life, and seek to clarify misunderstandings. Include the patient's surrogate in the conversation if possible, even when the patient retains decision-making capacity.

(b) Reassure the patient (and/or surrogate) that medically appropriate interventions, including appropriate symptom management, will be provided unless the patient declines particular interventions (or the surrogate does so on behalf of a patient who lacks capacity). [New content addresses gap in current guidance.]

(c) Negotiate a mutually agreed-on plan of care consistent with the patient's goals and with sound clinical judgment.

(d) Seek assistance from an ethics committee or other appropriate institutional resource if the patient (or surrogate) continues to request care that the physician judges not to be medically appropriate, respecting the patient's right to appeal when review does not support the request.

(e) Seek to transfer care to another physician or another institution willing to provide the desired care in the rare event that disagreement cannot be resolved through available mechanisms, in keeping with ethics guidance. If transfer is not possible, the physician is under no ethical obligation to offer the intervention.

As leaders within their institutions, physicians should encourage the development of institutional policy that:

(f) Acknowledges the need to make context sensitive judgments about care for individual patients.

(g) Supports physicians in exercising their best professional judgment.

(h) Takes into account community and institutional standards for care.

(i) Uses scientifically sound measures of function or outcome.

(j) Ensures consistency and due process in the event of disagreement over whether an intervention should be provided.

AMA Principles of Medical Ethics: I,IV,V

CEJA Report 2 – I-96
Medical Futility in End-of-Life Care

INTRODUCTION

In the course of clinical care of a critically ill patient it may become clear that the patient is inevitably dying, and that further intervention will do no more than prolong the active dying process. At this point, further intervention is often described as "futile." The Council has discussed related issues in previous reports, in particular affirming the ethical standing of withdrawing and withholding ineffective or inappropriate intervention and noting the constructive role that advance care planning can play in preempting difficult and conflicted situations.[1] However, the Council has thus far not directly defined "futility", a term whose meaning inherently involves a value judgment.[2] In this report, in response to a request from The Board of Trustees which notes the need for guidance on the matter, the difficulties of defining futility are balanced with the need to have an operational understanding of it.[3] The Council recommends defining futility on a case-by-case basis, taking full account of the context and individuals involved; it proposes a due process approach to achieving this case-by-case definition.

CIRCUMSTANCES WHERE FUTILITY JUDGMENTS ARE RELEVANT

Clinical paradigms of futile care have included life-sustaining intervention for patients in the persistent vegetative state, and resuscitation efforts for the terminally ill.[4,5,6,11] Other examples include the use of chemotherapy or surgery for advanced cancer and also less invasive treatments such as antibiotics or intravenous hydration for near moribund conditions. Futility can be relevant in non-life-threatening circumstances, for instance when a patient uses vitamins or popularized notions of meditation biofeedback to attempt cure of a chronic condition such as rheumatoid arthritis or macular degeneration. However, this report concerns itself with the use of interventions for life-threatening illness.

If the goals of one party differ from those of another, the question of futility is especially likely to arise.[7] In these situations one party, e.g. the proxy, often wants to pursue the goal of preserving life with or without much hope of future improvement while another party, e.g. the physician, sees that dying is inevitable and wishes to pursue the goal of comfort care. In such circumstances of disagreement it is likely that the physician, complying with proxy goals, intervenes with the sense that the only reasonable expectation for the intervention is to prolong the dying process. The parties may also hold reverse goals, for instance with the proxy believing that the physician is excessively pursuing life prolongation when death seems inevitable.

REASONS FOR DEFINING MEDICAL FUTILITY

There are many motivations for attaining clarity on what is meant by futility in end-of-life medical care, and how to manage relevant situations. First, advances in technological capacity have permitted intervention to sustain different biological systems even when cognizant human life is no longer possible, leading many to question the value of the intervention. Second, some of these dilemmas have not been resolvable within the systems of medical care, and they have resulted in widely publicized court cases, such as those of Wanglie and Gilgunn.[11,12] Patients, families, physicians and others would benefit if the medical system of care could handle such situations without need for recourse to the courts. Third, many have pointed out the expense of life-sustaining intervention. While life should not be lost for want of financial resources, nonetheless many have sought areas where costs can be saved in this time of concern over the large size of the health care budget. Fourth, people are living

A version of this Report was published as "Medical Futility in End-of-Life Care" (*JAMA.* 1999; 281: 937-941)

longer and conceptions of appropriate and inappropriate intervention for the increasingly large geriatric population are undergoing reexamination. Fifth, medical decision-making has moved from a more parentalistic mode to a patient-centered mode, consistent with the strong endorsement of autonomy as a value in society and medicine. However, several commentators are noting the limits to the autonomy model and the need to consider others and the community in decision-making in medicine. Futility judgments often contain implicit differences in the ethics model being used, with (for instance) physician standards and community standards being pitched against the autonomous drive for high levels of intervention. To avoid having futility judgments fall into the center of any of these struggles, clarity on the meaning of futility in this kind of clinical context would be helpful.

HAZARDS IN DEFINING MEDICAL FUTILITY

Rationing v. futility

Commentators have noted repeatedly that there is a danger that judgments about futility mask a covert motive to allocate resources. Both futility judgments and allocation decisions are sometimes necessary, but the two should be understood for what they are and not confused.[8] Rationing refers to the withholding of efficacious treatments which cannot be afforded. Futility refers to ineffective treatments. Efforts to define futility for the purpose of cost-saving measures would be just that, not rationing measures. Cost savings that could be realized if a futility standard were followed have been estimated to be large, but estimates based on clinical studies suggest that the savings would be minor.[9, 10] When life and death decisions are being made, cost savings motivations may seem offensive, and further, they are generally not a helpful or realistic feature for defining futility. Futility standards should not be used as covert mechanisms for cost savings by third party payers or others.

Turf and Parentalism

Since many problems of futility arise in the context of a disagreement between parties regarding what constitutes appropriate and what futile care, there is always a danger that the futility debate will be distorted by one party's defense of their authority over the others. In the Wanglie case, the patient’s husband successfully asserted that his substituted judgment about his wife’s view of appropriate medical intervention should trump the medical team’s view that intervention was futile.[11] In a reverse situation, the Massachusetts Superior Court jury upheld the prerogative of the profession to decline medical intervention that it considered futile for a patient named Gilgunn.[12] In such cases as Gilgunn's, and when physicians argue for professional standards, there is often a charge that professionals are parentalistically forcing their standards upon patients.[13, 14]

Value judgment v. Objective definition

Futility is intrinsically a value judgment, and reasonable people will disagree on what constitutes futile treatment in practice.[15] What constitutes futile care will differ depending on the medical setting (rural Africa or a Western hospital intensive care unit), goals for intervention (cure or prolong death until a relative arrives or maintain physiological parameters or secure the symbolic value of the intervention). In other words, this is a context-dependent and person-dependent assessment. A number of commentators have suggested that futility therefore cannot be specifically or concretely defined.[16, 17, 18] Others have instead emphasized the importance of including all stakeholders in assessments of futility and of maintaining a flexible standard that can change with the context.[19,20] Still others have emphasized that the real issue is the dialogue and negotiation of goals between the parties, replacing the issue of defining futility with structured deliberation about goals and a broader ethic of care[21, 22, 23]

Unilateral decisions v. Appropriate discourse

Occasionally, it may appear to a physician that the futility of an intervention allows avoidance of discussion. When an intervention is clearly medically inappropriate this is fair.[6] However, there is some risk in difficult decisions that a patient or patient's family may not agree with the physician's assessment, and that futility could be used as an excuse for avoiding difficult discussions. This should be avoided.

EXISTING EFFORTS TO DEFINE AND IMPLEMENT A POLICY ON FUTILITY

Definitions of futility have been proposed, based on a range of possible approaches. One approach is quantitative. The best known proposal in this category is one by Schneiderman and Jecker[23] that asserts that if the intervention does not work in more than one percent of attempts, it should be considered futile.

The quantitative standard is often combined with a qualitative approach, since what should count as a successful or, "acceptable" outcome for the above quantitative approach is a matter for subjective determination. This functional assessment usually concerns what constitutes a worth-the-effort quality of life. Some emphasize the prerogative of the patient or proxy to determine what counts as an acceptable outcome; others emphasize the role of the physician; others emphasize the importance of multi-party decision-making.

Another approach is to use physiological outcome. The problem here is the same as one that gave rise to the need for a concept of futility in the first place. Individuals do not judge the worth of an intervention by physiological outcomes alone; for instance, successful preservation of renal function should rank differently in the absence or presence of possible quality personal interaction. Similarly, one person's assessment of sufficient mental function is not another's. So physiological function alone cannot measure or define futility. A fourth possibility is to use the intent of the physician or patient/proxy in deciding on an intervention. This proposed standard would require physicians and patients/proxies to decline intervention that had the intent of prolonging dying. The difficulty here is two-fold. First, some intentions to prolong dying are justifiable, as in preserving organs for donation or waiting for a relative to arrive. Second, the occasions when futility disputes arise are usually such that intentions may be disputed and, even if clear, may be difficult to balance against those of another party.

A fifth possibility is to use community standards to ascertain which interventions will be provided. This approach has the merit of allowing different communities to define for themselves what they consider to be worthwhile on a scale of possible providable interventions for a full panoply of illness circumstances. The challenges for this approach inhere in securing valid prior decisions by a community, in accommodating a range of different opinions, in allowing suitable exceptions, and in maintaining periodic updates of the standards to keep apace of changes.[24, 25, 26, 27]

A sixth approach is to use institutional standards to define, proactively, what interventions are considered futile for defined circumstances. In the sense that an institution can define a community this standard could be the same as community standards. The unique challenges reside first, in finding a suitably public process of decision-making by the institution's community, and second in providing patients with appropriate informed consent and alternatives to the policy.

A seventh option is to use a due process approach.[28, 29, 30, 31] These process approaches would likely be adopted at the institutional level, but could be used at larger community or state levels. Therefore, there could be considerable overlap with either the community or institutional standards. The emphasis of the due process approach, however, is on process between parties rather than on definition of the parties. Professional standards, patient rights, intent standards, and family or community involvement can all be accommodated.

The process for declaring futility in a particular case would be defined by the institution or community, within parameters set by a regulatory body. For instance, the process might include: (1) Earnest attempts to deliberate over and negotiate prior understanding between patient, proxy and physician as to what constitutes futile care for the patient, and what falls within acceptable limits for the physician, family, and possibly also the institution. (2) Joint decision-making at the bedside between patient or proxy and physician. (3) Attempts to negotiate disagreements if they arise, with the assistants of consultants as appropriate, to reach resolution within all parties' acceptable limits. (4) Involvement of an institutional committee such as an ethics committee if disagreements are irresolvable. (5) If the outcome of the institutional process coincides with the patient's desires but the physician remains unpersuaded, arrangement may be made for transfer to another physician within the institution. (6) If the outcome of the process coincides with the physician's position but the patient/proxy remains unpersuaded, arrangements for transfer to another institution may be sought and, if done, should be supported by the transferring and accepting institution. (7) If transfer is not possible, the intervention in question need not be offered.

CONCLUSIONS

The Council on Ethical and Judicial Affairs finds great difficulty in assigning an absolute definition to the term futile care since it is inherently a value-laden determination.

Thus, the Council favors the due process approach for determining and withholding or withdrawing what is felt to be futile care. The due process approach can accommodate community and institutional standards, and the perspectives offered by the quantitative and functional approaches. It allows a hearing for patient or proxy assessments of worthwhile outcome, as well as for physician or other provider's perception of intent in treatment and whether the primary purpose of the treatment to be offered is to prolong the dying process without benefit to the patient or others with legitimate interest. It further has the advantage of providing a system for addressing the ethical dilemmas around end-of-life care without need for recourse to the court system.

The Council on Ethical and Judicial Affairs therefore recommends:

(1) That health care institutions, whether large or small, adopt a policy on medical futility.

(2) That policies on medical futility follow a due process approach. The following seven steps should be included in such a due process approach to declaring futility in specific cases.
  - (a) Earnest attempts should be made in advance to deliberate over and negotiate prior understandings between patient, proxy and physician on what constitutes futile care for the patient, and what falls within acceptable limits for the physician, family, and possibly also the institution.
  - (b) Joint decision-making should occur between patient or proxy and physician to the maximum extent possible.
  - (c) Attempts should be made to negotiate disagreements if they arise, and to reach resolution within all parties' acceptable limits, with the assistance of consultants as appropriate.
  - (d) Involvement of an institutional committee such as the ethics committee should be requested if disagreements are irresolvable.

(e) If the institutional review supports the patient’s position and the physician remains unpersuaded, transfer of care to another physician within the institution may be arranged.

(f) If the process supports the physician’s position and the patient/proxy remains unpersuaded, transfer to another institution may be sought and, if done, should be supported by the transferring and receiving institution.

(g) If transfer is not possible the intervention need not be offered.

REFERENCES

1. Council on Ethical and Judicial Affairs. “Decision near the end of life.” *JAMA*. 1992;267:2229-2233

2. Council on Ethical and Judicial Affairs, American Medical Association. *Code of Medical Ethics: Current Opinions with Annotations*. 1996-1997. Opinion 2.035 Futile Care.

3. AMA Board of Trustees Report 48-I-95 Quality Care at the End of Life, p. 14.

4. Paris JJ, Crone RK, Reardon F. “Physicians’ refusal of requested treatment: the case of Baby L.” *N Engl J Med*. 1990;322:1012-5.

5. Gray WA, Capone RJ, Most AS. “Unsuccessful emergency medical resuscitation--are continued efforts in the emergency department justified?” *N Engl J Med*. 1991;329:1393-98.

6. Blackhall LJ. “Must we always do CPR?” *N Engl J Med*. 1987;317:1281-84.

7. Kopelman L. “Ethical disputes over futile treatments.” *North Carolina Medical Journal*. 1995;56:458-459.

8. Jecker NS, Schneiderman LJ. “Futility and rationing.” *Am J Med*. 1992;92:189-196.

9. Lundberg GD. “National health care reform: the aura of inevitability intensifies.” *JAMA*. 1992;267:2521-4.

10. Teno JM, Murphy D, Lynn J, et al for the SUPPORT Investigators. “Prognosis-based futility guidelines: does anyone win?” *JAGS*. 1994;42:1202-1207.

11. Miles SH. “Informed demand for ‘non-beneficial’ medical treatment.” *N Engl J Med*. 1991;325:512-5.

12. Gilgunn v. Massachusetts General Hospital. Super. Ct. Civ. Action No. 92-4820, Suffolk Co., Mass., verdict, 21 April 1995.

13. Schneiderman LJ, Jecker N, Jonsen A. “Medical futility: its meaning and ethical implications.” *Annals Int Med*. 1990;112:949-54.

14. Capron AM. “Abandoning a waning life.” *Hastings Center Report*, 1995;July-August:24-6.

15. OBrien LA, Grisso JA, Maislin G, LaPann K, Krotki KP, Greco PJ, Siegart EA, Evans LK. “Nursing home residents’ preferences for life-sustaining treatments.” *JAMA*. 1995;274:1775-9.

16. Lantos JD et al. “The illusion of futility in clinical practice.” *Am J Med*. 1989;87:81-84.

17. Brody BA, Halevy A. “Is futility a futile concept?” *J Med Phil*. 1995;20:123-44.

18. Troug RD, Brett AS, Frader J. “The problem with futility.” *New Engl J Med*. 1992;326:1560-4.

19. Murphy DJ. “Lessons from Communities in Conversation: the Colorado experience.” *North Carolina Medical Journal*. 1995;56:428-430.

20. Kelly B. “A social worker’s view of futility policy issues.” *North Carolina Medical Journal*. 1995;56:427.

21. Emanuel L. “Structured deliberation to improve decisionmaking for the seriously ill.” *Hastings Center Report*. 1995;6:S14-S18. and Structured advance planning: is it finally time for physician action and reimbursement? JAMA 1995;274:501-503.

22. Zawacki BE. "The 'futility debate' and the management of Gordian knots." *J Clin Ethics*. 1995;6:112-128.

23. Schneiderman LJ, Jecker NS. "Beyond futility to an ethic of care." *Am J Med*. 1994;86:110-4.

24. Callahan D. "Medical futility, medical necessity: the-problem-without-a-name." *Hastings Center Report*. 1991;21:30-5.

25. Sugarman J. "A community policy on futility? a conversation of the North Carolina community." *North Carolina Med J*. 1995; 56: 415-7.

26. Emanuel LL, Emanuel EJ. "End-of-life care decisions: guided by communities of patients." *Hastings Center Report*. 1993; 23: 6-14.

27. Halevy A, Brody B. "A multi-institutional collaborative policy on medical futility." *JAMA*. 1996; 267: 571-4.

28. Kishwaukee Hospital, DeKalb, IL. "Futile care decision tree." *Medical Ethics Advisor*. 1995; December: 111.

29. Brody B, Halevy A for Baylor College of Medicine. "Baylor Guidelines" Guidelines on Institutional Policies on the Determination of Medically Inappropriate Interventions. January 24 1995 draft.

30. Tomlinson T, Czlonka D. "Futility and hospital policy." *Hastings Center Report*. 1995; 25: 28-35.

31. Norton RA for Tufts University School of Medicine. "A proposed policy on 'medically inappropriate CPR."

REPORTS AND OPINIONS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports and opinions, 1-13, were presented by John Glasson, MD, Chair (Opinions of the Council are indicated by an asterisk following the title):

REPORT 1 WITHDRAWN

2. FUTILE CARE*

HOUSE ACTION: FILED

Physicians are not ethically obligated to deliver care that, in their best professional judgment, will not have a reasonable chance of benefitting their patients. Patients should not be given treatments simply because they demand them. Denial of treatment should be justified by reliance on openly stated ethical principles and acceptable standards of care, as defined in opinions 2.03 and 2.095, not on the concept of "futility," which cannot be meaningfully defined.

(The Futile Care Opinion will appear in the next edition of Current Opinions with Annotations as Opinion 2.035 and is derived from Principles I and IV of the Principles of Medical Ethics.)

3. PRE-EMBRYO SPLITTING*

HOUSE ACTION: FILED

The technique of splitting in vitro fertilized pre-embryos may result in multiple genetically identical siblings.

The procedure of pre-embryo splitting should be available as long as both gamete providers agree. This procedure may greatly increase the chances of conception for an infertile couple or for a couple whose future reproductive capacity will likely be diminished. Pre-embryo splitting also can reduce the number of invasive procedures necessary for egg retrieval and the necessity for hormonal stimulants to generate multiple eggs. The use and disposition of any pre-embryos that are frozen for future use should be consistent with the Council's opinion on frozen pre-embryos. (Opinion 2.141)

The use of frozen pre-embryo identical siblings many years after one child has been born raises new ethical issues. Couples might wait until they can discover the mental and physical characteristics of a child before transferring a genetically identical sibling for implantation, they might sell their frozen pre-embryos based upon the outcome of a genetically identical child, or they might decide to transplant a genetically identical sibling based on the need to harvest the child's tissue.

The Council does not find that these considerations are sufficient to prohibit pre-embryo splitting for the following reasons:

1. It would take many years to determine the outcome of a child and most families want to complete their childbearing within a shorter time.
2. The sale of pre-embryos can and should be prohibited.